K030990

JUN 2 5 2003

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda Mini-Filter/S and Uni-Filter Junior

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

June 20, 2003

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda Mini-Filter/S
Datex-Ohmeda Uni-Filter Junior

COMMON NAME:

Disposable Bacterial/Viral Filter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

CAH Breathing Circuit Bacterial Filter 868.5260

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda Mini-Filter/S is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF Mini (K023641). The Datex-Ohmeda Uni-Filter Junior is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Mallinckrodt Barrierbac /S (K941536).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended use for the modified devices are the same as the predicates.

There has been no change to the fundamental scientific technology from the predicates.

The **Mini-Filter/S** incorporates electrostatic filter media into a housing made of translucent plastic.

Dimensions and Materials
- Diameter: 45 mm
- Length: 64 mm
- Housing: PP Polypropylene
- Filter: PP and acrylic fibers

Filtration efficiency:
- Filtration efficiency viral 99.98 %
- Filtration efficiency bacterial 99.999 %

The HMEF Mini is for use in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators.

It incorporates standard fittings for-
- 15 mm ID x 22 mm OD fitting to connect to the endotracheal tube or face mask
- 15 mm OD x 22 mm ID fitting to connect to the breathing circuit Y-piece
- A gas sampling port – female luer port with cap to allow sampling of expired CO2 gases

The modifications to the device are:

The Datex-Ohmeda Mini-Filter/S has the following differences when compared to the Datex-Ohmeda HMEF Mini predicate device:

- The devices differ in Moisture output and Breathing resistance

The main differences between the Datex-Ohmeda Mini-Filter/S and the predicate Datex-Ohmeda HMEF Mini (K023641) are due to fact that Mini-Filter/s is intended use only as breathing system bacterial and viral filter and HMEF Mini is intended use as breathing system bacterial and viral filter and also as heat and moisture exchanger. Mini-Filter/S is the same as the HMEF Mini without an HME-element.

The **Uni-Filter Junior** incorporates electrostatic filter media into a housing made of translucent plastic.

Dimensions and Materials
- Diameter: 59 mm
- Length: 64 mm
- Housing: PP Polypropylene
- Filter: PP and acrylic fibers

Filtration efficiency:
- Filtration efficiency viral 99.999 %
- Filtration efficiency bacterial >99.99999 %

The Uni-Filter Junior is for use in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators.

It incorporates standard fittings for-

- 15 mm ID x 22 mm OD fitting to connect to the endotracheal tube or face mask
- 15 mm OD x 22 mm ID fitting to connect to the breathing circuit Y-piece

The modifications to the device are:

The Datex-Ohmeda Uni-Filter Junior has the following differences when compared to the Mallinckrodt Barrierbac /S (K941536) predicate device:

- The devices differ in Breathing resistance and weight
- Filtration efficiency against virus
- Filtration efficiency against bacteria

The main differences between the Datex-Ohmeda Uni-Filter Junior and the predicate device Mallinckrodt Barrierbac /S (K941536) are due to fact that Uni-Filter Junior has better filtration efficiency, lower weight and lower resistance than predicate Mallinckrodt Barrierbac /S.

INTENDED USE as required by 807.92(a)(5)

Indication for use:

Datex-Ohmeda Filters can be used to provide filtration for reducing possible cross contamination between patient and equipment. Filters are for use in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators for filtering particles including bacteria, viruses and dust from CO2-absorbers.
The Mini-Filter/S can also be used for gas sampling. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda **Mini-Filter/S** is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF Mini (K023641).

The Datex-Ohmeda Mini-Filter/S has the following similarities to the Datex-Ohmeda HMEF Mini predicate device:
- have the same fundamental scientific technology and use the same operating principle
- are manufactured using the same processes
- constructed of identical materials
- Both the Mini-Filter/S and predicate HMEF Mini give efficient protection against transfer of bacteria / viruses between patients, personnel and equipment
-Filtration efficiency against virus
-Filtration efficiency against bacteria

The Datex-Ohmeda Mini-Filter/S has the following differences when compared to the Datex-Ohmeda HMEF Mini predicate device:

- The devices differ in Moisture output and Breathing resistance

The main differences between the Datex-Ohmeda Mini-Filter/S and the predicate Datex-Ohmeda HMEF Mini (K023641) are due to fact that Mini-Filter/s is intended use only as

breathing system bacterial and viral filter and HMEF Mini is intended use as breathing system bacterial and viral filter and also as heat and moisture exchanger. Mini-Filter/S is the same as the HMEF Mini without an HME-element.

In summary, the Datex-Ohmeda Mini-Filter/S, described in this submission is substantially equivalent to the predicate HMEF Mini (K023641).

The Datex-Ohmeda **Uni-Filter Junior** is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Mallinckrodt Barrierbac /S (K941536).

The Datex-Ohmeda Uni-Filter Junior has the following similarities to the Mallinckrodt Barrierbac /S (K941536) predicate device:
- have a similar indicated use
- have the same fundamental scientific technology and use the same operating principle

The Datex-Ohmeda Uni-Filter Junior has the following differences when compared to the Mallinckrodt Barrierbac /S predicate device:

- The devices differ in Breathing resistance and weight
- Filtration efficiency against virus
- Filtration efficiency against bacteria

The main differences between the Datex-Ohmeda Uni-Filter Junior and the predicate device Mallinckrodt Barrierbac /S (K941536) are due to fact that Uni-Filter Junior has better filtration efficiency, lower weight and lower resistance than predicate Mallinckrodt Barrierbac /S.

In summary, the Datex-Ohmeda Uni-Filter Junior, described in this submission is substantially equivalent to the predicate Mallinckrodt Barrierbac /S (K941536).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda Mini-Filter/S and Uni-Filter Junior complies with the safety standards below and are therefore safe and effective for the intended use. The devices have been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- ISO 9360:1992
- ISO 5356-1:1996
- ISO 594-1:1986
- ISO 594-2:1998
- EN 980:1996
- EN 1041:1998
- EN 13014
- ASTM F 1054-8721

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda Mini-Filter/S and Uni-Filter Junior as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2003

Mr. Joel Kent
Manager, Quality and /regulatory Affairs
Datex-Ohmeda
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K030990
Trade/Device Name: Datex-Ohmeda Mini-Filter/S and Uni-Filter Junior
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: March 27, 2003
Received: March 28, 2003

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030990

Device Name: Datex-Ohmeda Mini-Filter/S and Uni-Filter Junior

Indications For Use:

Datex-Ohmeda Filters can be used to provide filtration for reducing possible cross contamination between patient and equipment. Filters are for use in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators for filtering particles including bacteria, viruses and dust from CO2-absorbers.

The Mini-Filter/S can also be used for gas sampling.

The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030990